K 122840

DEC 1 4 2012

Special 510(k) Summary for compliance with CFR 807.92

September 12, 2012

1. General Provisions

Common Name:	Remote Controlled Radionuclide Applicator System (21 CFR 892.5700 – Product Code JAQ)
Proprietary Name:	CT HDR Tandem/Ring Applicator with Rectal Retractor
Owner Name	Mick Radio-Nuclear Instruments, Inc.
Address	521 Homestead Avenue Mount Vernon, New York 10550
Telephone	(914) 667-3999
Fax	(914) 665-8834
Contact Name	Chuck Smith
Contact email	chuck@micknuclear.com

2. Name of Predicate Device:

Device	Manufacturer	K Number
CT HDR Tandem/Ring Applicator with Rectal Retractor	Mick Radio-Nuclear Instruments, Inc.	K030110

3. Reason for this Special 510(k) Premarket Notification

The purpose of this Special 510(k) submission is to obtain clearance to market the CT HDR Tandem/Ring Applicator with Rectal Retractor (Catalog # 0407), with a modified two-piece Rectal Retractor.

4. Classification

This device is classified as a class II device according to 21 CFR 892.5700 .

5. Intended Use and Device Description

The Mick Radio-Nuclear Instruments, Inc. CT HDR Tandem/Ring Applicator with Rectal Retractor is intended for use in Brachytherapy. It is indicated for use where high dose rate (HDR) irradiation of the uterus and cervix is an accepted clinical practice. The applicator is designed to be compatible with the sealed sources found in High Dose Rate After-Loaders and do not modify or change the source, source packaging or remote source positioning mechanisms found on these after-loaders.

The applicator presents a stable and flexible delivery system for the administration of high dose rate irradiation of cancers of the uterus and cervix. The applicator offers several treatment options by including three different angles of Rings (30°, 45° & 60°) and nine different Tandems. The Tandems are offered in complementary angles to the three rings and in three different Tandem lengths for each angle (2cm, 4cm & 6cm from the ring axis). In addition, there are two sizes of Build-Up Caps (5mm & 7.5mm) that affix to the Rings that offer shielding to patient tissue and a Rectal Retractor is included. The entire applicator system is housed in a specially designed Sterilization Cassette, meant for both storage and sterilization. This applicator has been cleared by FDA since 2003.

The modification presented in this Special 510(k) allows for the removal of the paddle portion of the Rectal Retractor from the Rectal Retractor assembly. This facilitates easier cleaning by the user to prevent potential build-up of soil in the paddle. There are no other impacts to the applicator system in this modification. The intended use is unchanged.

The modification to a two-piece Rectal Retractor design is controlled through the Mick Radio-Nuclear design controls and is manufactured onsite at Mick Radio-Nuclear Instruments, Inc. The two-piece Rectal Retractor design does not introduce any new risks or potential negative impacts to the overall performance of the applicator.

6. Drawings

Schematic diagrams of the CT HDR Tandem / Ring Applicator with Rectal Retractor are provided in Tab I.

7. Manufacturing Process

This device is manufactured according to Good Manufacturing Practices (GMPs) as defined in 21CFR part 820. The processes used to fabricate these devices are similar to those used for the predicate device described in this 510(k) notification.

8. Biocompatibility

No new issues of biocompatibility are raised with regard to the modification of the Rectal Retractor of this device.

9. Summary of Substantial Equivalence

This device is similar in design and construction, utilizes the identical materials, and has the same intended use and performance characteristics to the predicate device. The modification to a two-piece Rectal Retractor incorporates a titanium mounting bracket and two additional titanium screws to affix the paddle to the Rectal Retractor assembly. The same grade of titanium used in the previous Rectal Retractor assembly is used for the additional components. The fundamental scientific technology is unchanged from the original predicate device. No new issues of safety or effectiveness are introduced by using this device.

Performance Test Results

a. In vitro Testing
   Not applicable to the modification for the device. By introducing this device, no new issues of safety or effectiveness are raised.

b. In vivo Testing
   Not applicable for the modification for the device.

10. Summary of Similarities and Differences

The design similarities/differences between the Rectal Retractor modification in this device and the original predicate device is/are:

The devices have the same basic design with the exception of the removable paddle component in the Rectal Retractor;
The devices have the same intended use;
The devices use the same materials;

A summary of the design controls in the modification of the Rectal Retractor are contained in Tab K.

11. Comparison Table

The Table below compares the modification of this device to the predicate device. Included in these tables are a comparison of the materials and intended uses of these devices.

	CT HDR Tandem/Ring Applicator with Rectal Retractor	**Modification to the CT HDR Tandem/Ring Applicator with Rectal Retractor**
K Number	K030110	To Be Determined
Intended Use	High dose rate brachytherapy treatment of the uterus and cervix.	High dose rate brachytherapy treatment of the uterus and cervix.
Shielding	No	No
Tandem Material	Titanium	Titanium
Colpostat Material	Titanium	Titanium
Build-Up Cap Material	Acetal	Acetal
Rectal Retractor Paddle Material	Acetal	Acetal
Rectal Retractor Paddle Mount Material	Not Applicable	Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mick Radio-Nuclear Instruments, Inc.
% Mr. Chuck Smith
Manager, Qulaity Assurance
521 Homestead Avenue
MOUNT VERNON NY 10550

DEC 1 4 2012

Re: K122840
Trade/Device Name: CT HDR Tandem/Ring Applicator with Rectal Retractor
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 12, 2012
Received: September 17, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122840

Device Name: **CT HDR Tandem/Ring Applicator with Rectal Retractor**

Indications for Use:

The Mick Radio-Nuclear Instruments, Inc. CT HDR Tandem/Ring Applicator with Rectal Retractor is indicated for High Dose Rate irradiation of the uterus and cervix. The modification that precipitated this Special 510(k) does not alter the indications for use.

Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Mary S Pastel

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____